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| 10/571,069 | 12/07/2006 | Hidemi Kurihara | 0230-0245PUS1 | 2459 |
| 2292 7590 11/17/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | | |
| EXAMINER MACTFARLANE, STACEY NEE | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/571,069

Applicant(s)

KURIHARA ET AL.

Examiner

STACEY MACFARLANE

Art Unit

1649

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 18-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-17 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 7/28/2008
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Claims 10-17 have been amended and claim 30 newly added as requested in the amendment filed on July 28, 2008. Following the amendment, claims 1-30 are pending in the instant application.

Claims 1-9 and 18-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on January 17, 2008.

Claims 10-17 and 30 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
3. Applicant's arguments filed on July 28, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections

Including New Grounds, Necessitated by Amendment

Claim Objections

4. Claim 30 is objected to because of the following informalities: typographical error, "Claims 10". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. As currently amended, Claims 10-17 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claim 10 is vague and indefinite in its recitation of periodontal transplant comprising an effective "tissue regenerating amount" of a neurotrophic factor and "a periodontically acceptable scaffold material". Absent an explicit definition within the disclosure, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of amounts that are effective for tissue regeneration or periodontically acceptable scaffold materials.
8. The terms "regenerates", "prevents" and "enhances" in claims 11-16 are relative terms which renders the claim indefinite. These terms are not defined by the claim, nor does the specification provide a standard for ascertaining the requisite degree. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
9. Claims 11-16 and 30 recite the limitation "therapeutically effective amount" in Claim 10. There is insufficient antecedent basis for this limitation in the claim. For Claim 30 this renders indefinite what component of the transplant "is in the range of 1×10^{-12} to 1×10^{-3} g".

10. Claim 30 is vague and indefinite in its recitation of an effective amount per "defect of furcation". There is no explicit definition within the disclosure such that the metes and bounds of a defect of furcation would be clear to one of ordinary skill in the art. Absent such recitation the limitation potentially raises issues under enablement, as to how a skilled artisan applies an effective amount per defect of furcation.
11. Claim 17 is indefinite for depending from an indefinite claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. As currently amended, Claims 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kirker-Head, Advanced Drug Delivery Reviews, 43:65-92, 2000.
14. Claims 10-16 are drawn to a periodontal transplant comprising a neurotrophic factor and a periodontically acceptable scaffold material.
15. As noted in section 7 above, there is no explicit definition within the specification for a "periodontically acceptable scaffold material" and thus the metes and bounds are unclear. The disclosure merely states, "'Transplant for periodontal tissue regeneration' is a material that enhances the regeneration of the periodontal tissue. In order to cause neurotrophic factors such as BDNF to act on a given in vivo site (e.g. a missing site of the alveolar bone) at a specified concentration, a certain scaffold is necessary. A

material working as such a scaffold is combined with a neurotrophic factor such as BDNF to provide the transplant of the present invention" [0100]. On page 8 of Remarks filed July 28, 2008, Applicant indicates that this "e.g. missing site of the alveolar bone" serves as a scaffold (at bullet 2) and that the term "transplant" is defined within the art as "a composition having the ability to transfer tissue from one part to another" (sentence bridging Remarks pages 8-9).

16. The Kirker-Head reference teaches that periodontal transplants comprising a bovine collagen sponge and bone morphogenic proteins were known in the art prior to filing (page 77, Section 2.4.5). The collagen sponge as taught by the reference is equivalent within the art to the Teruplug® embodiment in the working example of the instant specification (page 43). The Kirker-Head prior art teaches sponges imbued with bone morphogenic proteins (BMPs) enhance osseointegration and strengthen bone. The reference also teaches that BMPs are known to play a role in tooth regeneration, alveolar ridge augmentation, dental pulp vitality and dentine repair and mineralization. The reference also identifies BMPs as known in the art to neurotrophic and neuroprotective functions (abstract, page 67 section 1.4, particularly at cite 93). Therefore, Claims 10-16 fail to distinguish over the prior art.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. As currently amended, Claims 17 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over as applied to claims 10-16 above, and further in view of Tsuboi et al., J Dent Res, 80(3): 881-886 (2001); Kurihara et al., J Periodontol, 74(1):76-84, January 2003; and Harada et al., Arch Histol Cytol, 66(2): 183-194, May 2003.

Claim 17 is drawn to a periodontal transplant comprising a neurotrophic factor, wherein the factor is the instantly-elected brain-derived neurotrophic factor (BDNF). Claim 30 is drawn to the periodontal transplant wherein the therapeutically effective amount is in the range of 1×10^{-12} to 1×10^{-3} g per tooth or defect of furcation. As stated in sections 9 and 10 above claim 30 is vague and indefinite. Since the claim 30 lacks antecedent basis, it is unclear what component of the transplant is required to be within the recited range. In the interest of compact prosecution Examiner is interpreting it to recite the neurotrophic factor, and specifically the instantly-elected BDNF, is required to be within that range.

The Kirker-Head reference teaches that periodontal transplants comprising a periodontically acceptable scaffold (collagen sponge) material and neurotrophic factor

were known in the art prior to filing and have the effect of enhancing osseointegration, strengthening bone, playing a role in tooth regeneration, alveolar ridge augmentation, dental pulp vitality and dentine repair and mineralization.

The Kirker-Head reference does not teach the transplant comprising the instantly elected BDNF, however, the teachings of Tsuboi et al., Kurihara et al., and Harada et al., demonstrate that BDNF was known in the art to as a specific trophic factor for periodontal cells and tissues. The combined teachings of Tsuboi, Kurihara, and Harada demonstrate that BDNF was well-known in the art prior to filing as inducing proliferation of periodontal cells (Tsuboi Figure 3), that neurotrophins and their receptors are expressed during tooth development, play a role in periodontal disease and periodontal tissue regeneration (Kurihara abstract), and that BDNF plays a specific role in the regeneration of periodontal tissues (Harada et al.) Specifically, Tsuboi et al. demonstrate that BDNF in the range of 1×10^{-12} to 1×10^{-3} g enhances periodontal cell proliferation.

It would have been obvious to one of ordinary skill in the art to combine the transplant product comprising a neurotrophic factor as taught by Kirker-Head with teachings of Tsuboi, Kurihara, and Harada regarding the specific effects of the instantly-elected BDNF on periodontal tissue. One of ordinary skill in the art would recognize that, with respect to neurotrophic factors, there are a finite number of predictable compositions available for use with the periodontal transplant. In combination each of the prior art elements are merely acting in the same manner as disclosed separately. Thus, it would have been within the technical grasp of one of ordinary skill in the art to

combine the prior art elements to create a periodontal transplant that comprises the neurotrophic factor BDNF, with a reasonable expectation of success. Therefore, the invention as a whole is *prima facie* obvious, if not actually anticipated by the reference.

Conclusion

20. No Claim is allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M,W and ALT F 7 am to 3:30, T & R 5:30 -5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649